must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than December 24, 1986.

A. **Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Jack's Fork Bancorporation, Inc.*, Mountain View, Missouri; to acquire 100 percent of the voting shares of the successor by merger to Farmers State Bank of Texas County, Houston, Missouri.

B. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *MBI Bancshares, Inc.*, Kansas City, Missouri; to acquire 100 percent of the voting shares of The Bank of Kansas City, Kansas City, Missouri, and thereby indirectly acquire Westport Bank, Kansas City, Missouri.

Board of Governors of the Federal Reserve System, December 12, 1986.

Barbara R. Lowrey,

Associate Secretary of the Board.

[FR Doc. 86-28342 Filed 12-16-86; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Additions to Senior Executive Service Performance Review Board Membership

Title 5, U.S.C. 4314(c)(4), of the Civil Service Reform Act of 1978, Pub. L. 95-454, requires that the appointment of Performance Review Board members be published in the Federal Register.

On October 2, 1986, the Department of Health and Human Services' PRB membership was published in the Federal Register. The following members are hereby added to that membership:

James F. Dickson, III

Dated: December 8, 1986.

Thomas S. McFee,

Assistant Secretary for Personnel Administration.

[FR Doc. 28254 Filed 12-16-86; 8:45 am]

BILLING CODE 4150-04-M

Alcohol, Drug Abuse, and Mental Health Administration

Reestablishment of the Board of Scientific Counselors

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776) and the Anti-Drug Abuse Act of 1986 (Pub. L. 99-570, section 501(j)), the Administrator, Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), announces the reestablishment, effective January 5, 1987, of the following committee:

Board of Scientific Counselors, National Institute of Mental Health

The duration of this committee is continuing unless formally determined by the Administrator, ADAMHA, that termination would be in the best public interest.

Dated: December 11, 1986.

Donald Ian Macdonald, M.D.,

Administrator, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 86-28222 Filed 12-16-86; 8:45am]

BILLING CODE 4160-20-M

Food and Drug Administration

[Docket No. 86E-0456]

Determination of Regulatory Review Period for Purposes of Patent Extension; Buspar

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Buspar and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension and applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Buspar (buspirone hydrochloride), which is indicated for the management of anxiety disorders and the short-term relief of symptoms of anxiety. Based on this approval, Mead Johnson & Co. now seeks patent term restoration.

FDA has determined that the applicable regulatory review period for Buspar is 5,281 days. Of this time, 3,896 days occurred during the testing phase of the regulatory review period, while 1,385 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective: April 16, 1972. The applicant claims that clinical studies for the drug began on October 22, 1976. However, FDA records indicate that the notice of claimed investigational exemption (IND) for the durg became effective on April 16, 1972.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: December 15, 1982. FDA has verified the applicant's claim that the new drug application for the drug (NDA 18-731) was initially submitted on December 15, 1982.

3. The date the application was approved: September 29, 1986. FDA has

verified the applicant's claim that NDA 18-731 was approved on September 29, 1986.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculation of the actual periods for patent extension. In its application for patent extension, this applicant seeks 730 days of patent extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 17, 1987, submit to the Dockets Management Branch (address above written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 15, 1987, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 10, 1986.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 86-28200 Filed 12-16-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86E-0455]

Determination of Regulatory Review Period for Purposes of Patent Extension; Pepcid

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Pepcid and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Pepcid (famotidine), which is indicated in the short-term treatment of active duodenal ulcer, maintenance therapy for duodenal ulcer patients at reduced dosages after healing of active ulcer, and treatment of pathological hypersecretory conditions. Based on this approval, Yamanouchi Pharmaceutical Co., Ltd., now seeks patent term restoration.

FDA has determined that the applicable regulatory review period for Pepcid is 1,917 days. Of this time 1,438 days occurred during the testing phase of the regulatory review period, while 479 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* July 18, 1981. FDA has verified the applicant's claim that the notice of claimed investigational exemption (IND) for the drug became effective on July 18, 1981.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* June 24, 1985. FDA has verified the applicant's claim that the new drug application for the drug (NDA 19-462) was initially submitted on June 24, 1985.

3. *The date the application was approved:* October 15, 1986. FDA has verified the applicant's claim that NDA 19-462 was approved on October 15, 1986.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 730 days of patent extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 17, 1987, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 15, 1987, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch beween 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 10, 1986.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 86-28201 Filed 12-16-86; 8:45 am]

BILLING CODE 4160-01-M